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Strauch et al.

(10) **Patent No.: US 8,726,907 B2**
(45) **Date of Patent: May 20, 2014**

(54) **SURGICAL DRAPE WITH SEPARABLE ELEMENTS**

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(*) Notice: Subject to any disclaimer, the term of this patent is extended or adjusted under 35 U.S.C. 154(b) by 47 days.

(21) Appl. No.: **13/155,219**

(22) Filed: **Jun. 7, 2011**

(65) **Prior Publication Data**

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Related U.S. Application Data

(60) Provisional application No. 61/352,045, filed on Jun. 7, 2010, provisional application No. 61/357,637, filed on Jun. 23, 2010, provisional application No. 61/490,432, filed on May 26, 2011.

(51) **Int. Cl.**
A61B 19/08 (2006.01)

(52) **U.S. Cl.**
USPC **128/849**; 128/856

(58) **Field of Classification Search**
CPC A61B 19/08; A61B 19/12
USPC 128/849, 851, 856; 24/304, 399–404, 24/409–411, 584.1, 585.1, 585.11–585.12, 24/DIG. 38–DIG. 39
See application file for complete search history.

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Primary Examiner — Tatyana Zalukaeva
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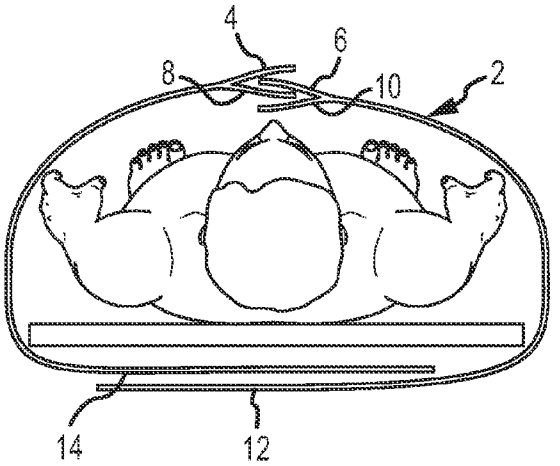
(57) **ABSTRACT**

The present disclosure relates to a one piece customized disposable surgical drape to be used in any surgery, and more specifically to a one piece customized disposable surgical drape that includes one or more of the following: (1) a patient drape for use with a standalone non-draped image acquisition device (requiring circumferential access to the patient); (2) a patient drape for use with a standalone non-draped image acquisition device with image guidance navigation technology; (3) the means to provide temporary sterile coverage of an underlying sterile field; (4) the means to provide sterile separation of at least a portion, if not the entire temporary sterile coverage; and (5) the means to provide covering of the undersurface of the operating surface and enclosing any suspended medical devices, wires, cables, tubes, etc.

7 Claims, 14 Drawing Sheets



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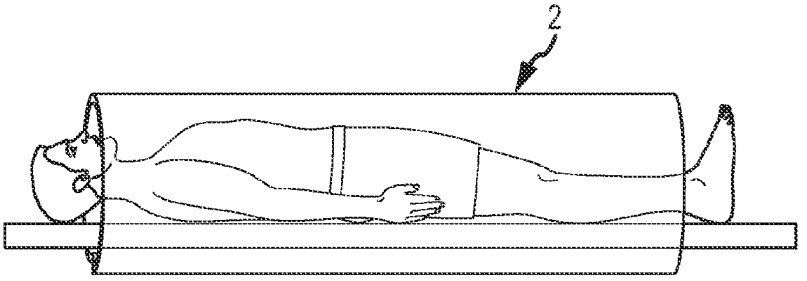


FIG.1A

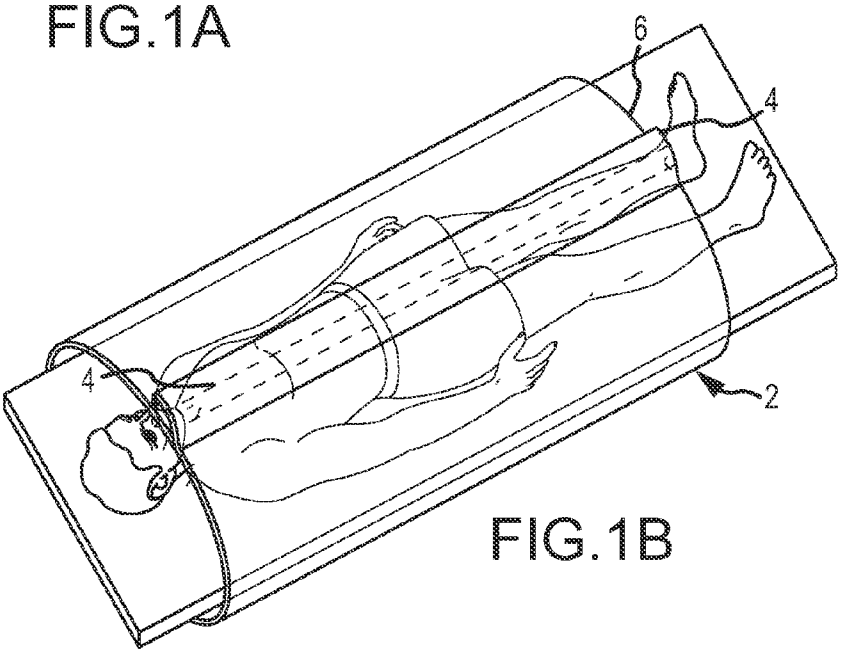


FIG.1B

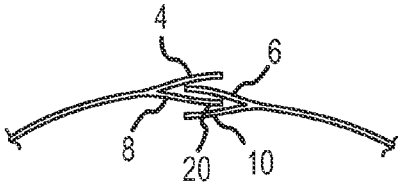
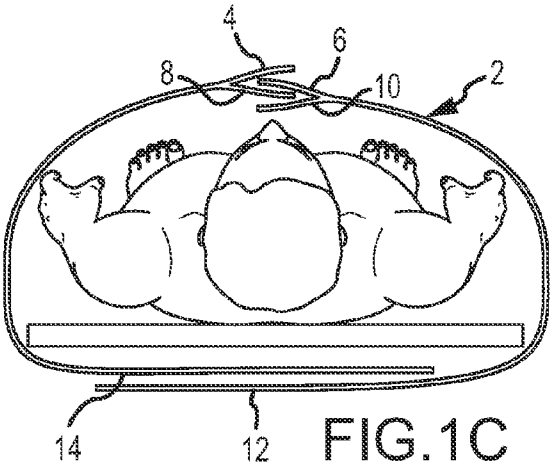


FIG.1D



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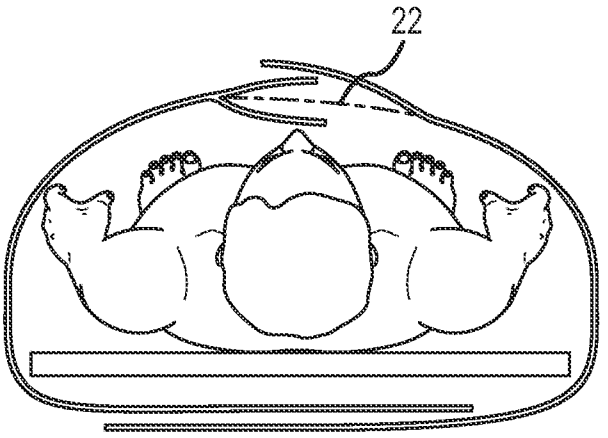


FIG.2A

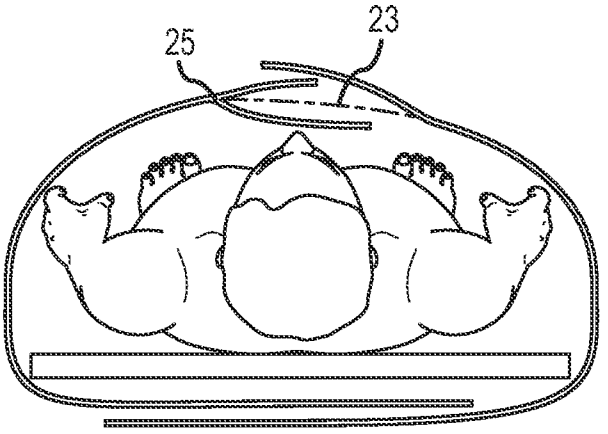
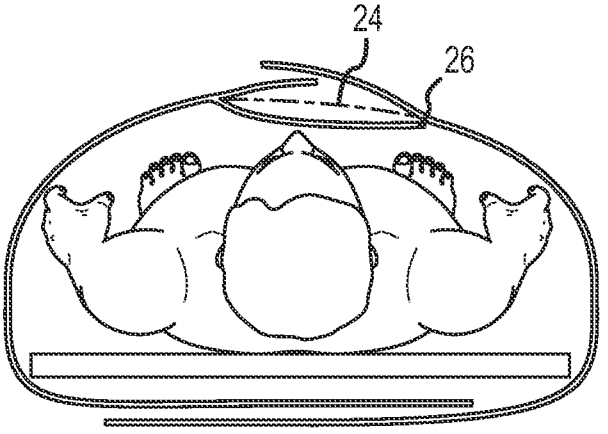


FIG.2B



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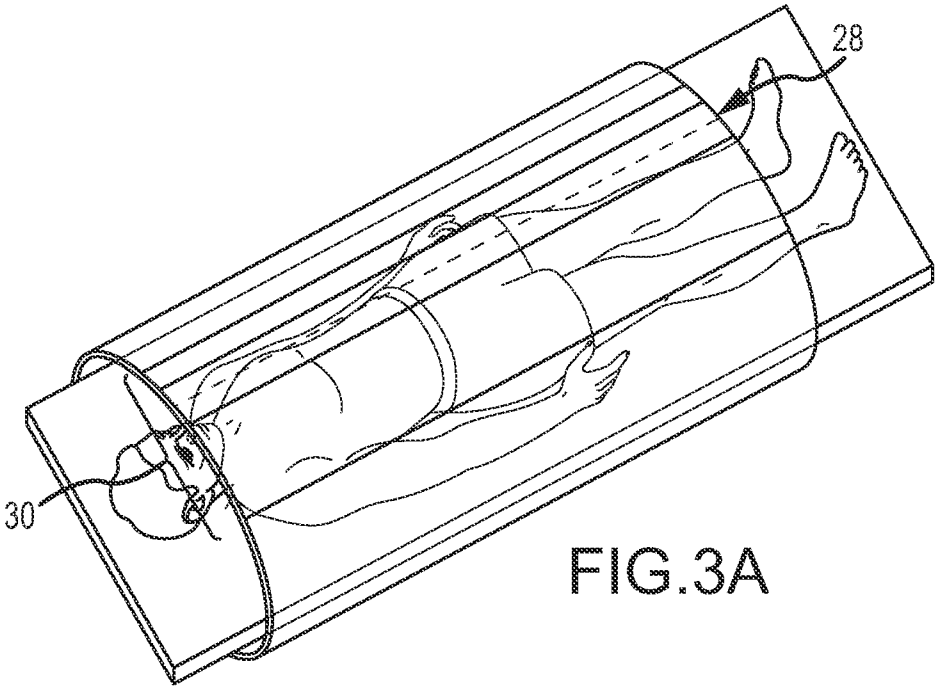

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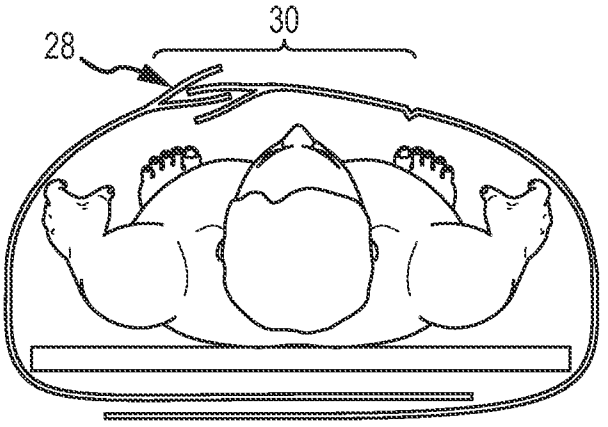


FIG.3B

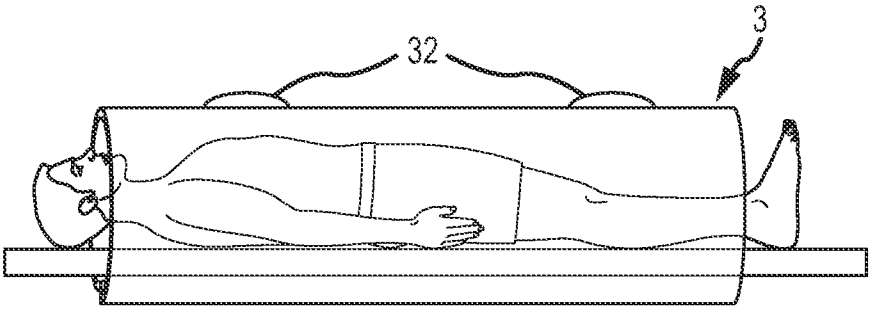
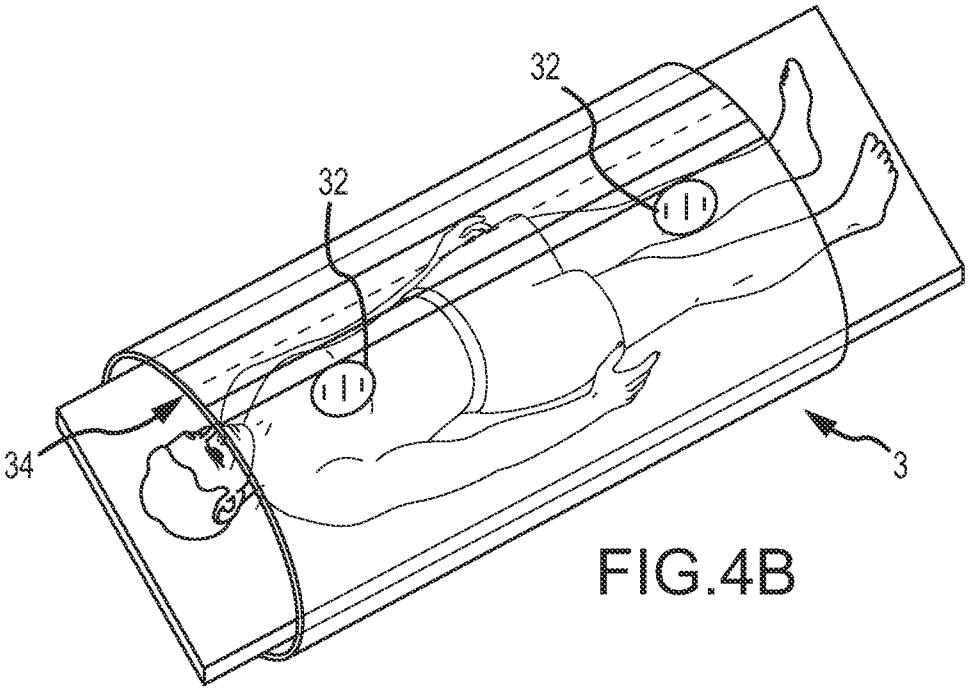


FIG.4A



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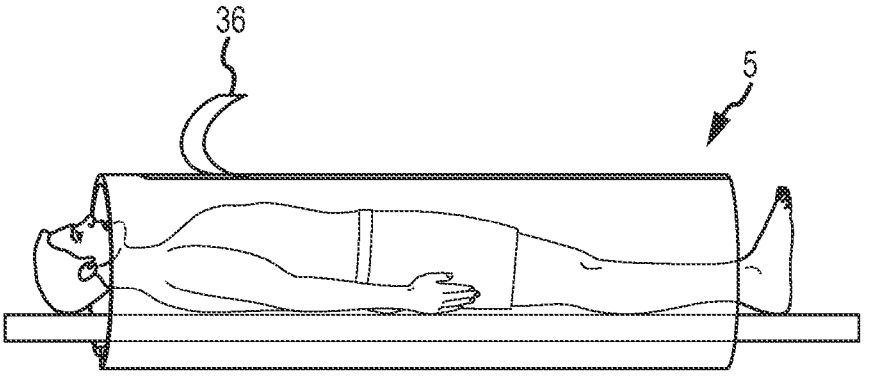

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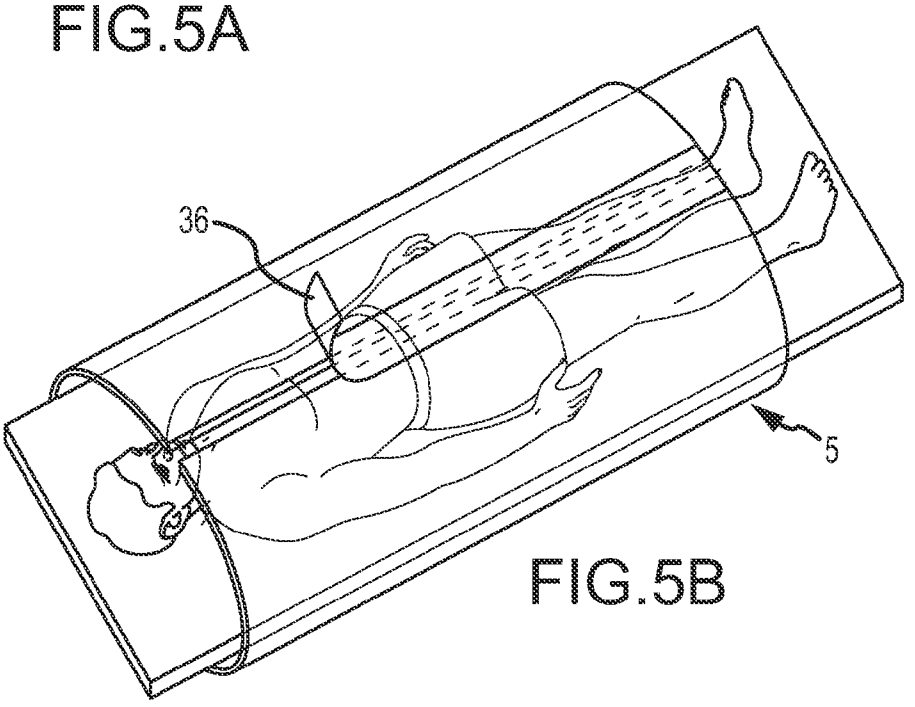


FIG.5B

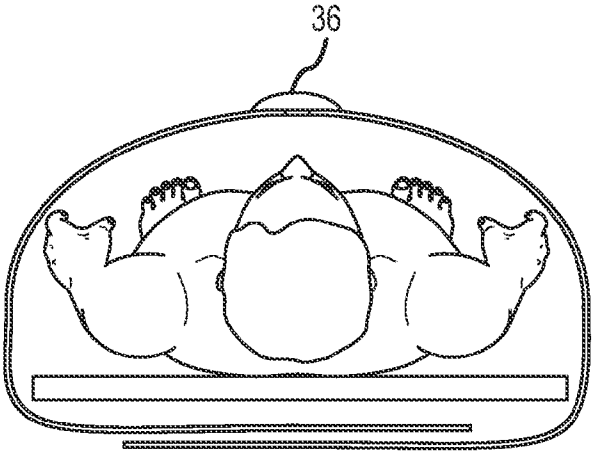


FIG.5C

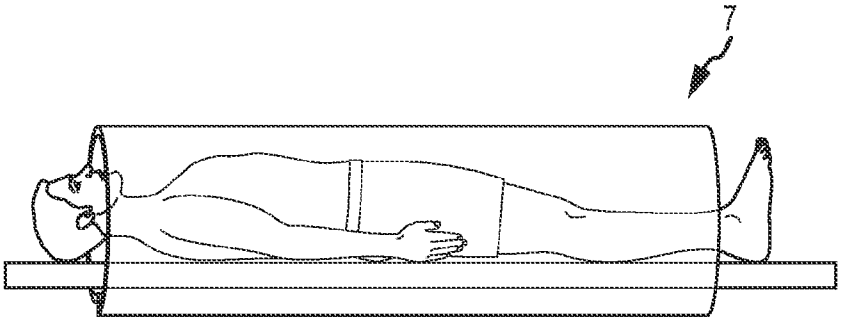
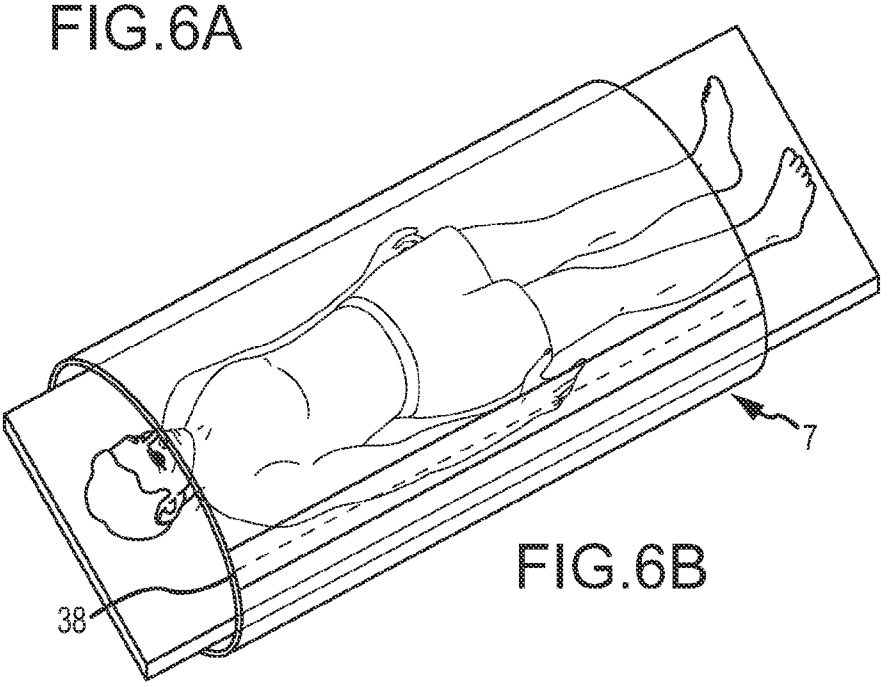


FIG.6A



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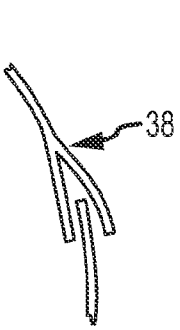
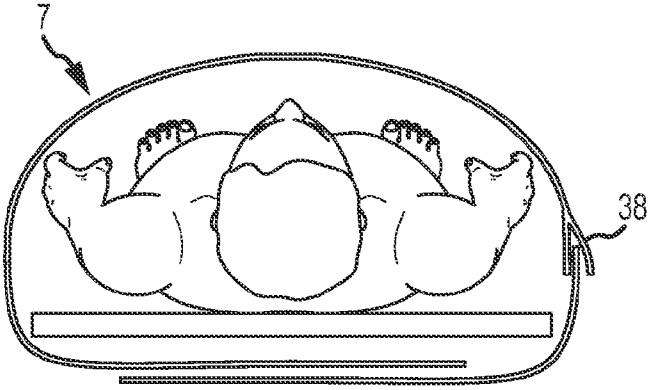


FIG.6D



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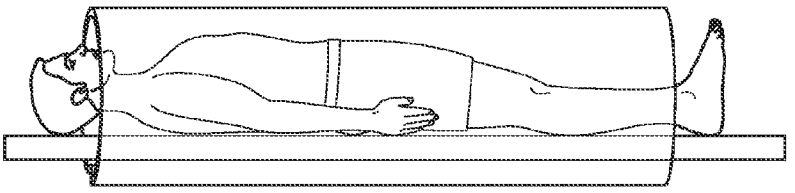

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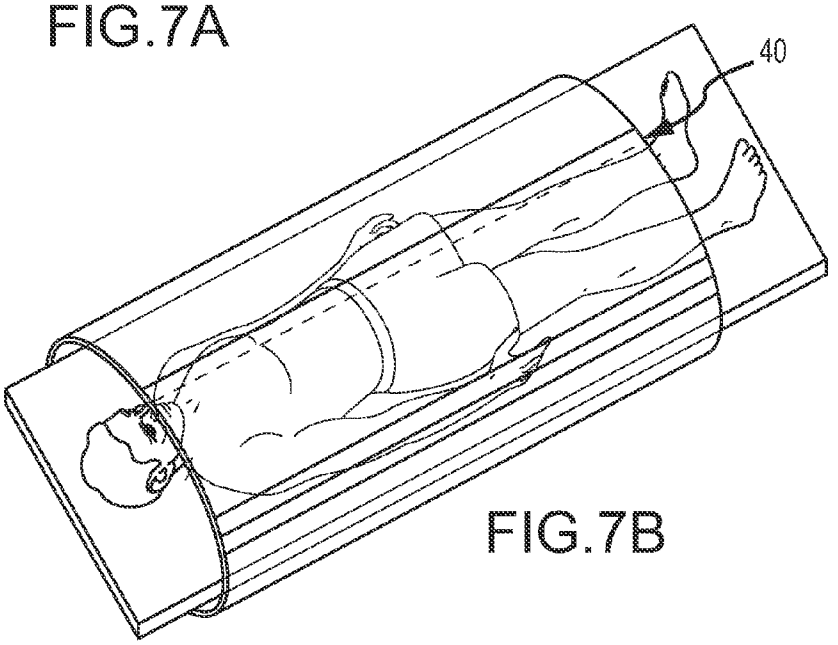

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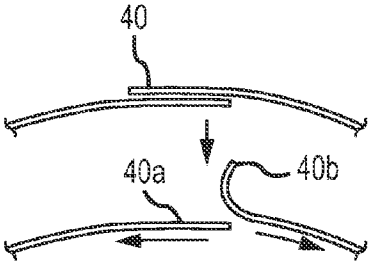

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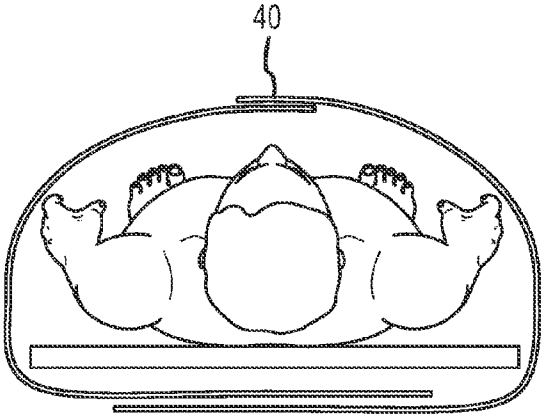


FIG.7C

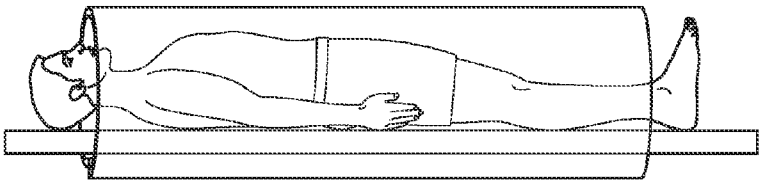


FIG.8A

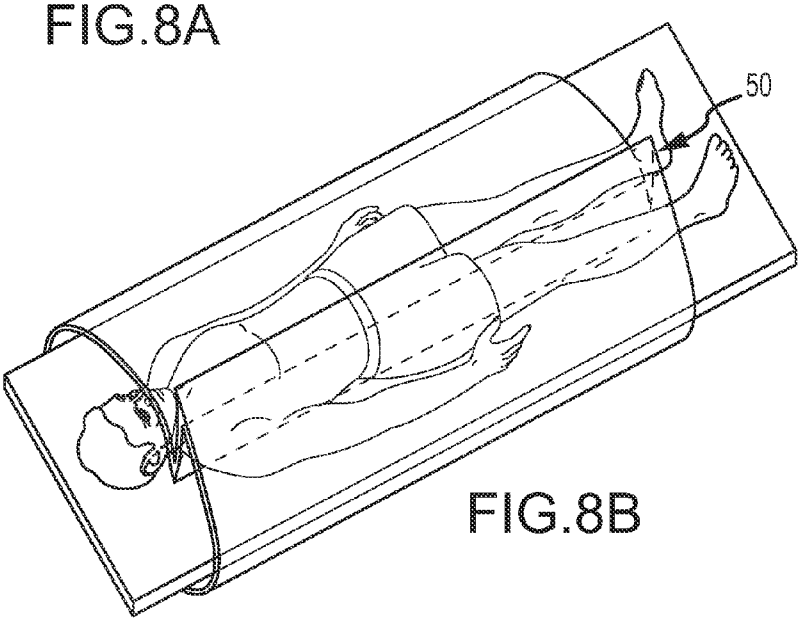
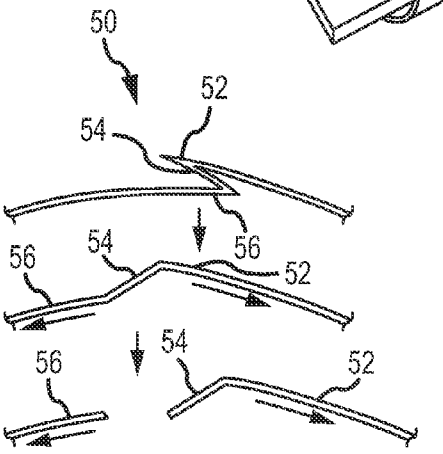


FIG.8B



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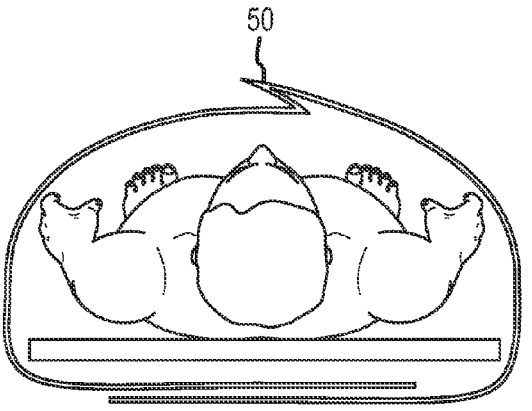


FIG.8C

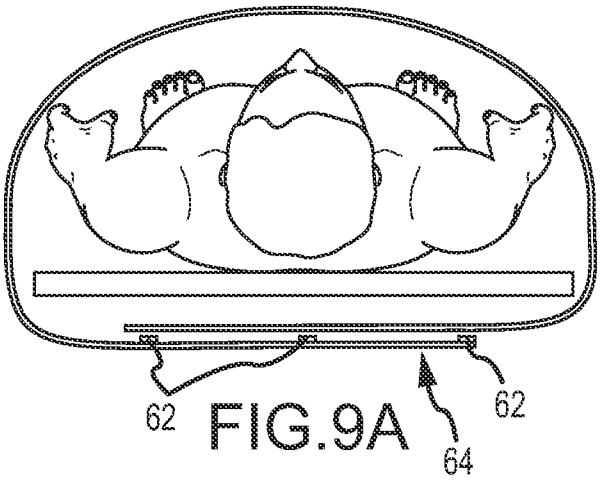


FIG.9A

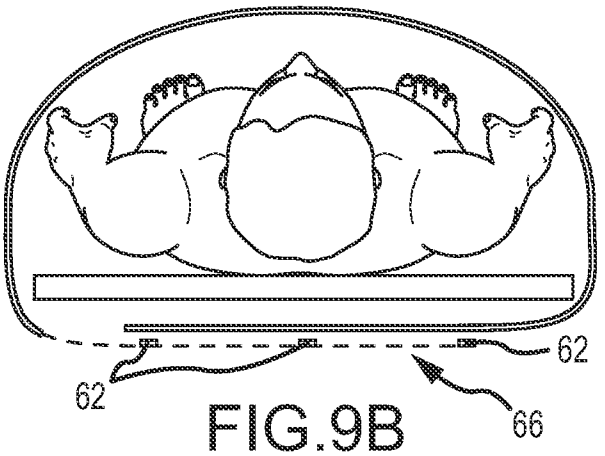


FIG.9B

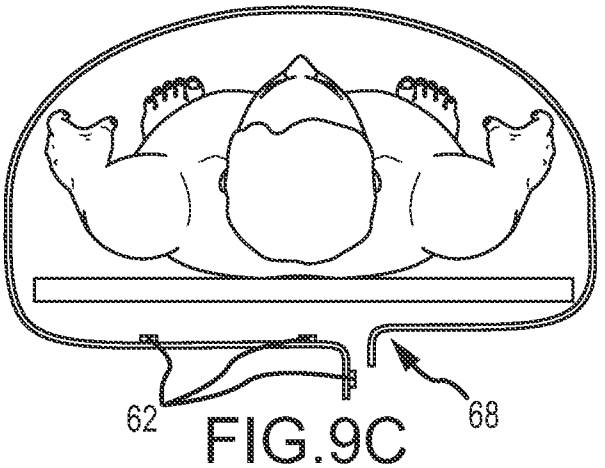


FIG.9C

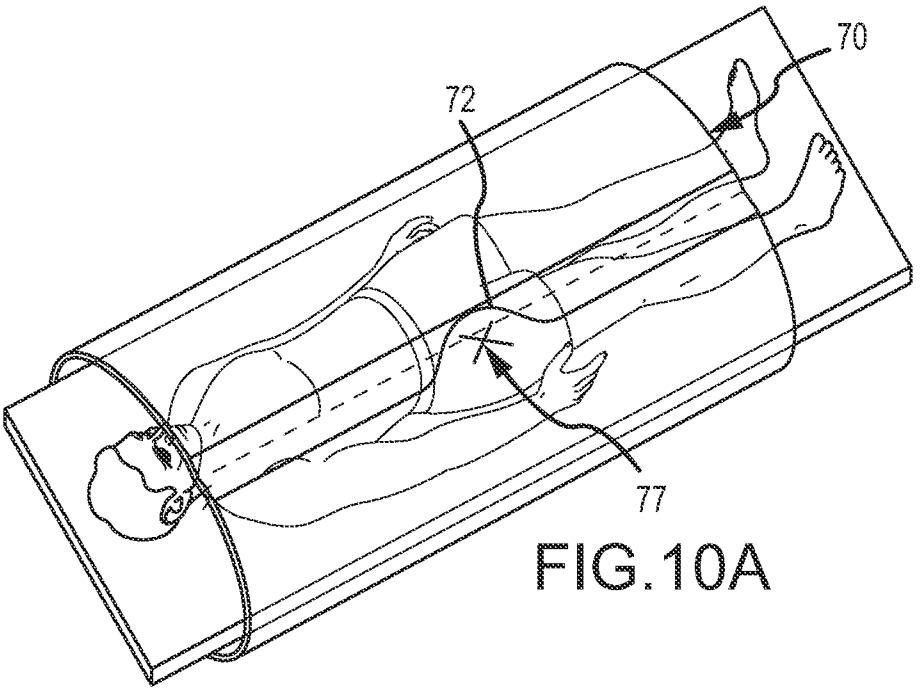


FIG.10A

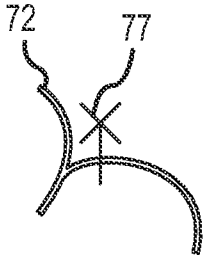


FIG.10B

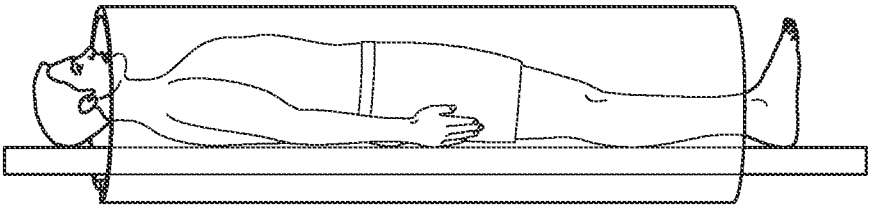


FIG.11A

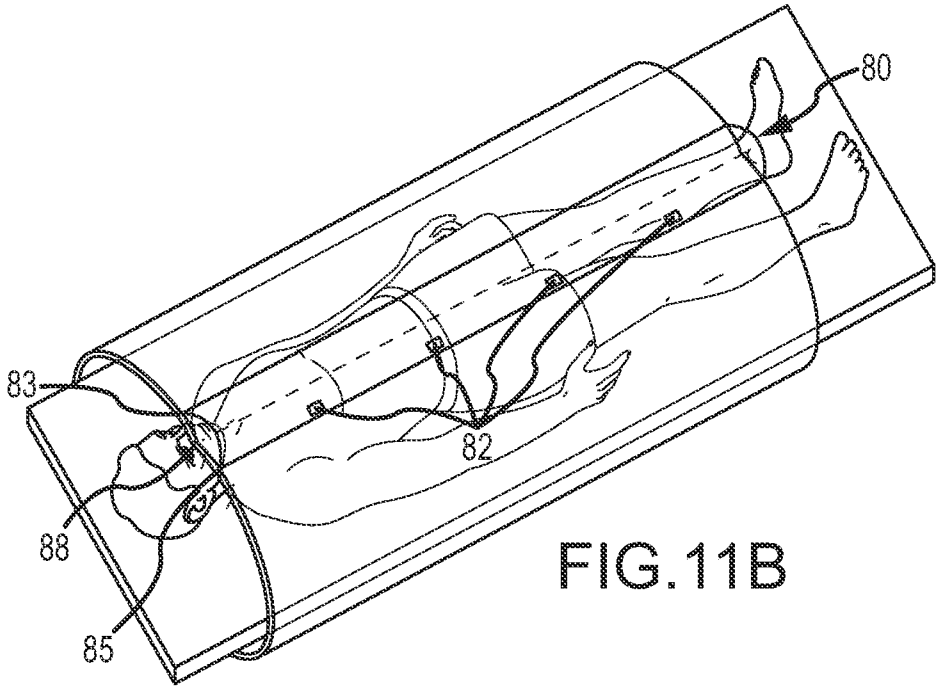
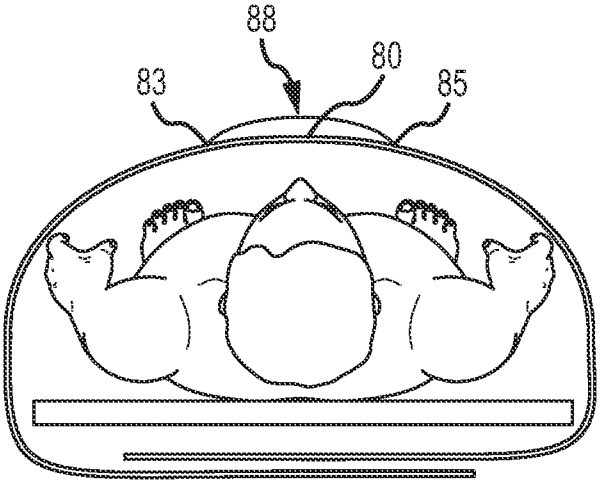


FIG.11B



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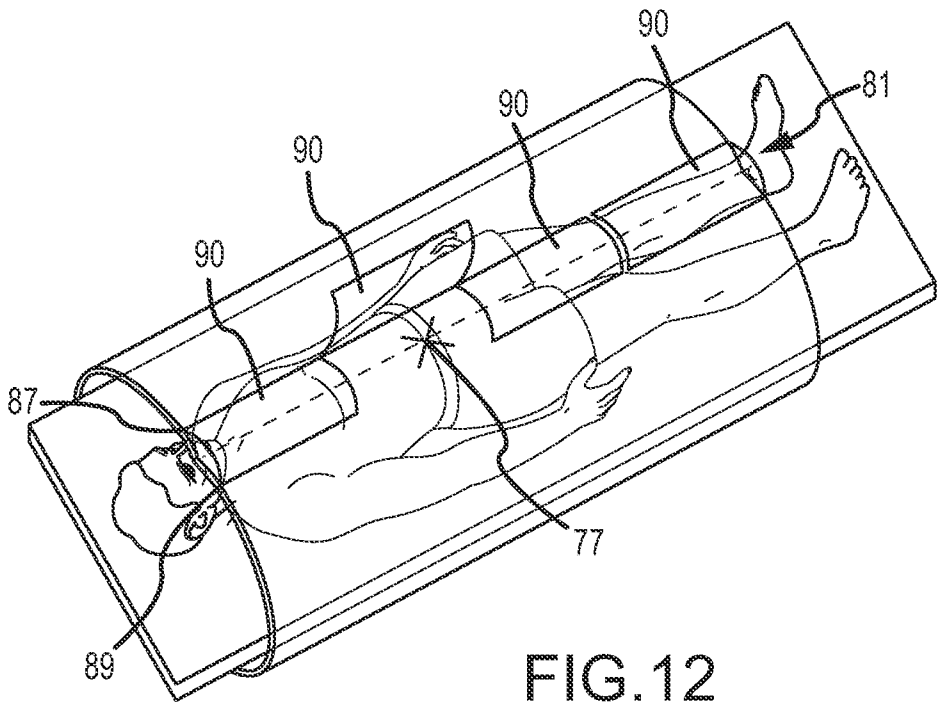

FIG.12

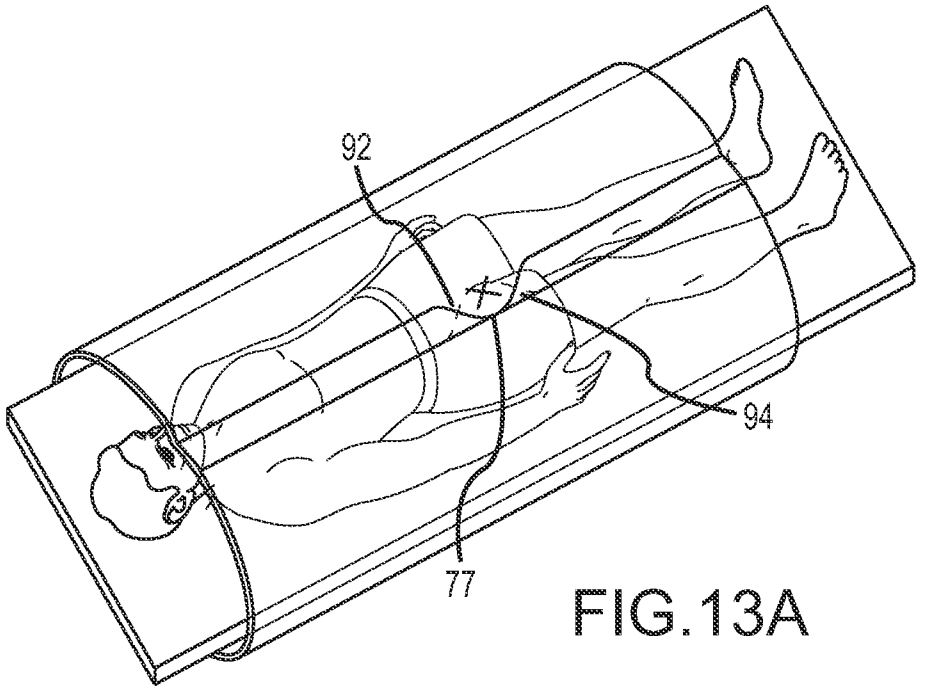

FIG.13A

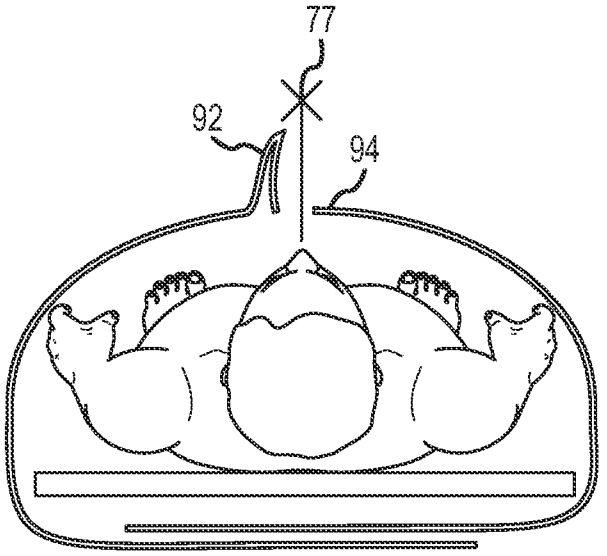

FIG.13B

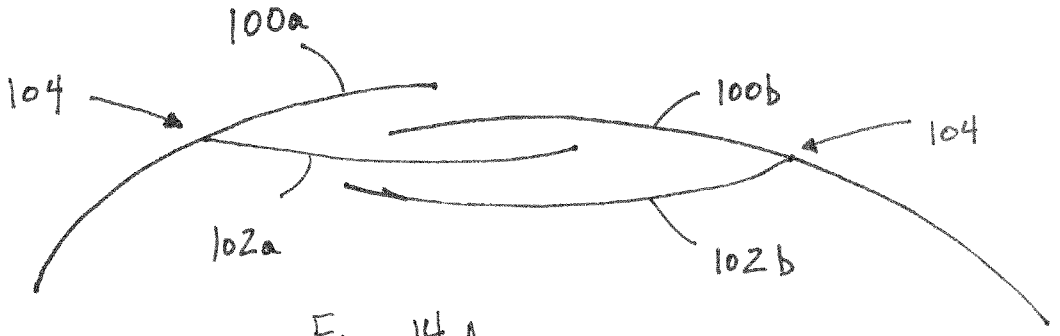

Fig. 14A

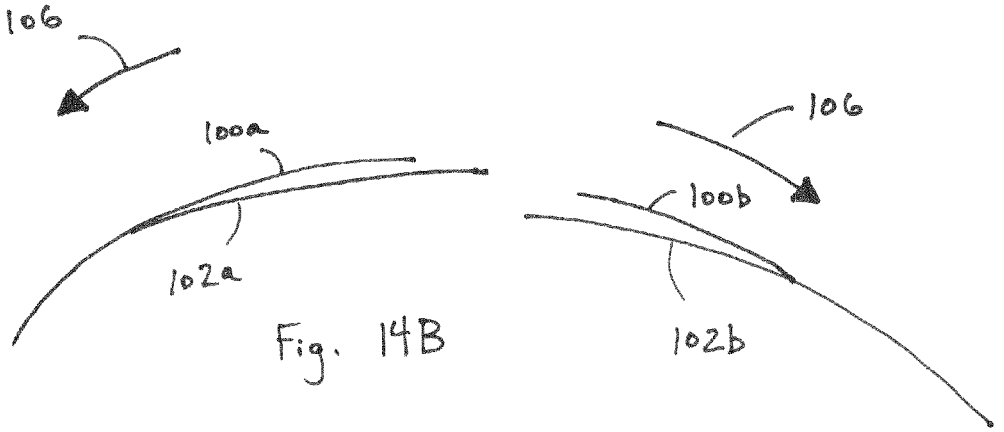

Fig. 14B

SURGICAL DRAPE WITH SEPARABLE ELEMENTS

The present application claims priority from U.S. Provisional Application Nos. 61/352,045, filed Jun. 7, 2010, 61/357,637 filed Jun. 23, 2010, and 61/490,432 filed May 26, 2011, the entire disclosures of which are hereby incorporated by reference in their entireties.

FIELD OF THE INVENTION

This disclosure relates to orthopedic surgery, and more specifically to a one piece customized disposable surgical drape that includes one or more of the following: (1) a patient drape for use with a standalone non-draped image acquisition device (requiring circumferential access to the patient); (2) a patient drape for use with a standalone non-draped image acquisition device with image guidance navigation technology; (3) the means to provide temporary sterile coverage of an underlying sterile field; (4) the means to provide sterile separation of at least a portion, if not the entire temporary sterile coverage; and (5) the means to provide covering of the undersurface of the operating surface and enclosing any suspended medical devices, wires, cables, tubes, etc.

BACKGROUND OF THE INVENTION

Individuals may suffer a variety of spinal disorders involving degenerative disc disease, spine deformity, herniated discs, traumatic injuries and congenital anomalies. Some of these pathologies may require surgery on the affected region to relieve the individual from pain and/or prevent further injury to the spine and neural structures. Spinal surgery may involve decompression of the spinal cord and nerves, stabilization of painful or unstable motion segments and correction of deformity. The surgical procedure will vary depending on the nature and extent of the pathology. In all instances, it is critical that a sterile field be maintained throughout the procedure, regardless of its duration. Published standards and recommended practices exist, including those developed by the Association of periOperative Registered Nurses (AORN), which provide guidelines to be used by a surgical team when caring for their patients in an operative setting.

It is the goal of the surgical team to prevent the contamination of an open surgical wound by isolating the operative site from the surrounding nonsterile environment. The surgical team accomplishes this by creating and maintaining the sterile field and by following aseptic principles aimed at preventing microorganisms from contaminating the surgical wound. Sterile surgical drapes establish an aseptic barrier minimizing the passage of microorganisms from nonsterile to sterile areas. Sterile drapes should be placed on the patient, furniture, and equipment to be included in the sterile field, leaving only the incisional site exposed. During the draping process, only scrubbed personnel should handle sterile drapes. The drapes should be held higher than the operating room bed with the patient draped from the prepped incisional site out to the periphery. According to the standards published by AORN, once the sterile drape is positioned, it should not be moved or rearranged.

Several disadvantages exist regarding current methods for maintaining sterility throughout a spinal surgery. First, current makeshift draping procedures (fitting a multitude of drapes around the patient) are time consuming and thus prolong the length of the procedure. Second, current methods of draping the various equipment and surgical implements are complicated and challenging to accomplish efficiently. Third, maintaining a sterile field throughout the procedure is more challenging, especially when using radiological equipment. Finally, current draping systems do not provide a well-accepted means to provide temporary sterile coverage of underlying sterile equipment tables and trays.

Currently, navigation technology in conjunction with three dimensional ("3D") radiographic technology is being utilized to make surgical techniques more time-efficient, accurate, and safer. Using 3D imaging by utilizing an "O-arm" device (with or without navigation technology) presents challenges both in regard to appropriate draping and maintenance of a sterile field as well as maneuverability of the 3D imaging device in and out of the sterile field. "C-arm" surgical cases can present similar challenges.

In regards to the above-referenced radiological equipment, to create a sterile "tunnel" with drapes through which the arm can pass (as it rises from the unsterile 'below table' region to the sterile 'above table region') is not only cumbersome and time-consuming, but also a potential risk to the sterile field if such a method were to fail (e.g., an unsterile drape falls into the sterile field as the radiological device arm propels it superiorly).

Sleeve type drapes for covering an 'O-arm' have been utilized. Aside from the fact that they are time-intensive and cumbersome, these drapes can contaminate the field if they become displaced as the O-arm is enclosing around the OR table. Also, the sag of the drape off the underside of the most superior aspect of the O-arm can block the reference frame from being properly read and displayed by the monitor. Finally, given the effort necessary in draping the 3D radiological device itself, the surgeon may decide to leave the device in the field and operate around it, thereby avoiding having to re-drape again for later imaging. Thus, the surgeon is compromised as he/she attempts to perform the surgery with the 3D device left in place.

Currently, many surgeons utilizing a 3D acquisition device in conjunction with navigation technology have devised makeshift draping systems that, while draping the patient rather than the radiographic device for reasons stated above, attempt to maintain complete protection to the underlying sterile field. The reference frame attached to the patient's anatomy (often the spinous process) must protrude through the disposable, makeshift draping system (formed by two approximated half sheets secured by steri-strips) in order to be readable by the navigation monitor. However, the reference frame cannot be exposed to the underside of the undraped (and thus non-sterile) 3D radiographic device above. Therefore, the reference frame is often covered by a piece of clear plastic to maintain the sterility of the reference frame attached to the patient's anatomy, but at the same time, allow for the reference frame to be readable by the navigation monitor. This piece of clear plastic also serves another purpose—it covers the medial borders of both approximated half-sheets that run longitudinally along the sagittal midline of the patient through which the reference frame neck protrudes. When removing this makeshift draping system, the plastic cover is removed, followed by the fall of both half sheets laterally off the table.

Numerous problems exist in regard to draping when attempting to use 3D devices and concomitantly maintain a sterile field. In regard to the makeshift draping system described above, several concerns are raised. First, any breach in the makeshift drape system (e.g. gap, tear or opening) can potentially cause the drape to fail in its intended purpose—protecting the patient from infection by preventing microorganisms from making their way into the skin opening of the surgical site. For instance, the plastic covering of the

reference frame and medial borders of the two approximated half sheets often does not extend the entire length of the half-sheets. Thus, if the 3D radiographic device swings into position over any portion of the approximated half-sheets uncovered by the plastic cover, the medial borders are potentially exposed. When the half-sheets fall laterally to the floor during the removal process, it is possible that contamination of the underlying sterile field could occur as the medial edges of the half-sheets make contact. Second, the time in gathering the components of such a makeshift draping system (2 half-sheets, two non-piercing hemostats/clamps, steri-strips, and a cut out plastic covering) and placing into position is labor and time-intensive. Certainly, it can be expected that any relatively new scrub technician will not have such components ready in an efficient manner.

The accuracy of integration of the anatomical information provided by the 3D data acquisition device and the navigation system depends on the technology utilized, the readability of the reference frame, and the stability of the reference frame. Under the assumption that medical providers are content with the technological capabilities of the system, the two remaining variables regarding accuracy of integration of anatomical data and monitored (navigated) surgical instruments are the readability and stability of the reference frame. Under the assumption that medical providers remain meticulous in avoidance of reference frame displacement, then the remaining factor affecting the accuracy of the system is based on the readability of the reference frame. A thin, clear plastic is therefore desirable to minimize refraction of the infrared light thereby minimizing any inaccuracy that may inherently exist with indirect communication of the navigation monitor and the reference frame.

Thus, multiple problems exist in prior art draping apparatus and methods, and in particular providing a sterile field where a separation is necessary to accommodate one or more pieces of equipment used during the surgery. Because the use of makeshift draping is both time and labor intensive, does not adequately address the helpful 'under the table' enclosure, and fails to preserve sterile technique, many surgeons have opted to simply not drape the sterile fields as well as the 3D radiographic device. The present disclosure addresses all of these challenges and other shortcomings in the prior art.

SUMMARY OF THE INVENTION

This disclosure relates to orthopedic surgery, and more specifically to a one piece customized disposable surgical drape that includes one or more of the following: (1) a patient drape for use with a standalone non-draped image acquisition device (requiring circumferential access to the patient); (2) a patient drape for use with a standalone non-draped image acquisition device with image guidance navigation technology; (3) the means to provide temporary sterile coverage of an underlying sterile field; (4) the means to provide sterile separation of at least a portion, if not the entire temporary sterile coverage; and (5) the means to provide covering of the undersurface of the operating surface and enclosing any suspended medical devices, wires, cables, tubes, etc.

According to one embodiment, an apparatus is disclosed wherein a draping device is utilized for concomitant use of navigation technology and 3D imaging, featuring 'through plastic (or lens) readability, sterile longitudinal separation, and under-table wrapping capability, as described in greater detail below.

According to one embodiment, an apparatus is disclosed wherein a draping device further allows for navigation readability of one or more reference frames both indirectly (through plastic or lens) and directly (without plastic or lens). The level of sterility depends on the option chosen. Sterile longitudinal separation of the draping device in one or more locations and under-table wrapping capabilities are similarly provided with this embodiment.

According to one embodiment, an apparatus is disclosed wherein a draping device is provided to offer temporary coverage for an underlying sterile field (without navigation technology). This may involve 2D or 3D imaging without navigation (e.s. no reference frame) or temporary sterile coverage of a sterile or equipment table. The drape of this embodiment has a longitudinal sterile separation element, and the under-table wrapping capability may also be provided. The plastic component may be provided, or alternatively the draping device may be manufactured as a plastic or transparent paper drape, or similar transparent material.

Navigation and 3D Imaging Use

When performing a 3D imaging or a radiological procedure, the equipment and imaging technology often requires that a patient has a sterile reference frame attached to and protruding from his/her anatomy that needs to be readable by a navigation monitor while 3D imaging is obtained. The surgical drape device according to one embodiment is designed to drape the sterile field rather than the radiological device. It accommodates a surgeon's preference, as it allows for navigation readability of the attached reference frame through a clear plastic material or optical lens while the 3D acquisition is taking place.

Incorporation of a clear plastic region or lens into the drape device preserves sterility of the underlying reference frame and surgical field, while simultaneously allowing for readability of the reference frame by the navigation device. In spine surgery, the surgical drape permits reference frame placement in the posterior cervical, thoracic and lumbar spine axial positions, as well as the posterior superior iliac crest position (on either side). The drape device therefore accommodates different anatomical placements of the reference frame (such as when utilized in maxillofacial/ENT surgery and pelvic trauma) and/or various positions of the monitor, such as for cranial positioning.

Sterile Separation of Two Opposing Edges

The draping device according to varying embodiments provides at least one location for achieving a longitudinal separation of the drape, while still maintaining the sterility of the separating edges, and allows for easy removal of the drape. The two separating halves of the drape can fall to their respective side of the OR table in a sterile manner, thus exposing the underlying sterile field for continuance of surgery. Several unique arrangements and mechanisms for sterile separation are described below.

This particular embodiment is critical where a surgical patient is draped, rather than a radiological device. However, the sterile separation of two opposing edges may also be applied to a drape utilized in a variety of non-radiographic imaging situations where temporary coverage of a sterile field is necessary. Examples of such uses are also described below.

Under-Table Wrap Up Component

According to another embodiment, the drape device allows for complete enclosure of the patient not only above the table but also underneath the table (in the unsterile region). The portion of the drape underneath the table will clasp in one or more locations to enclose the various wires, cords, and tubes (e.g. neuromonitoring wires, catheter, etc.) and allow for easy and efficient positioning (entrance and exit) of any required non-sterile 2D or 3D image data acquisition device around the table and patient.

When 2D or 3D imaging is used as a standalone device (and thus without concomitant use of navigation technology), the drape still offers desirable improvements over the prior art in the sterile separation of two longitudinal opposing edges (e.g. 'double underbite' separation) as well as the 'under-the-table' wrapping component, both making surgery safer and more efficient.

In one embodiment, a drape is provided with a selectively separable portion intersecting a lateral point proximal to a midpoint of a predetermined width of the drape. In a further embodiment, a drape comprises a selectively separable portion intersecting a lateral point that is proximal to a midpoint of a predetermined width of the drape and within a middle third of the predetermined width. In a further embodiment, a drape comprises a selectively separable portion intersecting a lateral point that is proximal to a midpoint of a predetermined width of the drape and wherein the midpoint is equidistant from the first peripheral edge and the second peripheral edge of the drape.

This Summary of the Invention is neither intended nor should it be construed as being representative of the full extent and scope of the present disclosure. The present disclosure is set forth in various levels of detail in the Summary of the Invention as well as in the attached drawings and the Detailed Description of the Invention, and no limitation as to the scope of the present disclosure is intended by either the inclusion or non-inclusion of elements, components, etc. in this Summary of the Invention. Additional aspects of the present disclosure will become more readily apparent from the Detailed Description, particularly when taken together with the drawings.

The above-described benefits, embodiments, and/or characterizations are not necessarily complete or exhaustive, and in particular, as to the patentable subject matter disclosed herein. Other benefits, embodiments, and/or characterizations of the present disclosure are possible utilizing, alone or in combination, as set forth above and/or described in the accompanying figures and/or in the description herein below. However, the Detailed Description of the Invention, the drawing figures, and the exemplary claim set forth herein, taken in conjunction with this Summary of the Invention, define the invention.

BRIEF DESCRIPTION OF THE DRAWINGS

The accompanying drawings, which are incorporated in and constitute a part of the specification, illustrate embodiments of the disclosure and together with the general description of the disclosure given above and the detailed description of the drawings given below, serve to explain the principles of the disclosures.

It should be understood that the drawings are not necessarily to scale. In certain instances, details that are not necessary for an understanding of the disclosure or that render other details difficult to perceive may have been omitted. It should be understood, of course, that the disclosure is not necessarily limited to the particular embodiments illustrated herein.

FIG. **1**A is a side elevation view of a patient with a draping device according to one embodiment of the present disclosure;

FIG. **1**B is a top perspective view of the draping device shown in FIG. **1**A;

FIG. **1**C is an end view of the draping device shown in FIG. **1**A;

FIG. **1**D is a partial sectional view of the draping device shown in FIG. **1**A;

FIG. **2**A is an end view of a patient with a draping device according to one embodiment of the present disclosure;

FIG. **2**B is another end view of the patient with a draping device according to one embodiment of the present disclosure;

FIG. **2**C is another end view of the patient with a draping device according to one embodiment of the present disclosure;

FIG. **3**A is a top perspective view of the draping device according to one embodiment of the present disclosure;

FIG. **3**B is an end view of the draping device shown in FIG. **3**A;

FIG. **4**A is a side elevation view of a patient with a draping device according to one embodiment of the present disclosure;

FIG. **4**B is a top perspective view of the draping device shown in FIG. **4**A;

FIG. **5**A is a side elevation view of a patient with a draping device according to one embodiment of the present disclosure;

FIG. **5**B is a top perspective view of the draping device shown in FIG. **5**A;

FIG. **5**C is an end view of the draping device shown in FIG. **5**A;

FIG. **6**A is a side elevation view of a patient with a draping device according to one embodiment of the present disclosure;

FIG. **6**B is a top perspective view of the draping device shown in FIG. **6**A;

FIG. **6**C is an end view of the draping device shown in FIG. **6**A;

FIG. **6**D is a detailed sectional view of the draping device shown in FIG. **6**A;

FIG. **7**A is a side elevation view of a patient with a draping device according to one embodiment of the present disclosure;

FIG. **7**B is a top perspective view of the draping device shown in FIG. **7**A;

FIG. **7**C is an end view of the draping device shown in FIG. **7**A;

FIG. **7**D is a sectional view of the longitudinal sterile separation for the draping device shown in FIG. **7**A;

FIG. **8**A is a side elevation view of a draping device according to one embodiment of the present disclosure;

FIG. **8**B is a top perspective view of the draping device shown in FIG. **8**A;

FIG. **8**C is an end view of the draping device shown in FIG. **8**A;

FIG. **8**D is a sectional view of the draping device shown in FIG. **8**A;

FIG. **9**A is an end view of a draping device according to one embodiment of the present disclosure;

FIG. **9**B is another end view of a draping device according to one embodiment of the present disclosure;

FIG. **9**C is another end view of a draping device according to one embodiment of the present disclosure;

FIG. **10**A is a top perspective view of a draping device according to one embodiment of the present disclosure;

FIG. **10**B is an end view of the draping device shown in FIG. **10**A;

FIG. **11**A is a side elevation view of a draping device according to one embodiment of the present disclosure;

FIG. **11**B is a top perspective view of the draping device shown in FIG. **11**A;

FIG. **11**C is an end view of the draping device shown in FIG. **11**A;

FIG. **12** is a top perspective view of the draping device according to one embodiment of the present disclosure;

FIG. **13**A is a top perspective view of a draping device according to one embodiment of the present disclosure;

FIG. **13**B is an end view of the draping device shown in FIG. **13**A; and

FIG. **14**A is an end view depicting a feature of a draping device;

FIG. **14**B is an end view depicting a feature of a draping device;

DETAILED DESCRIPTION

By way of providing additional background, context, and to further satisfy the written description requirements of 35 U.S.C. §112, the following references are incorporated by reference in their entireties for the express purpose of explaining the nature of the surgical procedures referred to herein and to further describe the various tools and other apparatus commonly associated therewith: U.S. Pat. No. 6,309,395 to Smith et al.; U.S. Pat. No. 6,142,998 to Smith et al.; U.S. Pat. No. 7,014,640 to Kemppanien et al.; U.S. Pat. No. 7,406,775 to Funk, et al.; U.S. Pat. No. 7,387,643 to Michelson; U.S. Pat. No. 7,341,590 to Ferree; U.S. Pat. No. 7,288,093 to Michelson; U.S. Pat. No. 7,207,992 to Ritland; U.S. Pat. No. 7,077,864 Byrd III, et al.; U.S. Pat. No. 7,025,769 to Ferree; U.S. Pat. No. 6,719,795 to Cornwall, et al.; U.S. Pat. No. 6,364,880 to Michelson; U.S. Pat. No. 6,328,738 to Suddaby; U.S. Pat. No. 6,290,724 to Marino; U.S. Pat. No. 6,113,602 to Sand; U.S. Pat. No. 6,030,401 to Marino; U.S. Pat. No. 5,865,846 to Bryan, et al.; U.S. Pat. No. 5,569,246 to Ojima, et al.; U.S. Pat. No. 5,527,312 to Ray; U.S. Pat. No. 6,314,959 to Griesbach et al.; and U.S. Pat. Appl. No. 2008/0255564 to Michelson.

U.S. Patent Publication Nos. 2010/0186754 to Carrez et al. and 2010/0192960 to Rotolo are hereby incorporated by reference in their entireties herein for the express purpose of providing description of various materials and methods of production for surgical drapes.

According to varying embodiments disclosed herein, a draping device and method for using the same is described. As one of or ordinary skill in the art will appreciate, embodiments of the present disclosure may be constructed of materials known to provide, or predictably manufactured to provide the various aspects of the present disclosure. These materials may include, for example, cotton, paper, silk, polyethylene, and polyester. These materials may also include, for example, carbon fiber, ABS plastic, polyurethane, rubber, latex, synthetic rubber, and other fiber-encased resinous materials, synthetic materials, polymers, and natural materials. In another embodiment, some or all elements of the device, or portions of some or all of the elements, are substantially transparent.

Embodiments of the present disclosure present several advantages over the prior art including, for example, the efficacy of the procedure, the sterility of the procedure, the lower risk of infection, etc. Further, the advantages of the device according to various embodiments disclosed herein allows improved viewing of the area intended for surgery. Thus, the presence of one or more transparent areas is one aspect of this disclosure

Referring now to FIGS. **1**A-**14**, several embodiments of the present invention are shown. Referring in particular to FIGS. **1**A-**9**C, the drape according to one embodiment (RWD1) has been designed to meet all basic design requirements considered to be mandatory for operating room use. Multiple alternatives are shown for RWD1.

The drape shown in FIGS. **1**A-**9**C, according to varying embodiments, includes a surgical drape, which may be made of a variety of different materials described herein. The surgical drape is of sufficient length and width to encompass a human patient and/or an operating table and associated wires, cables, trays, tools, and instruments, including but not limited to 3D radiographic equipment, which is used during the course of a sterile surgical procedure. The drape according to one embodiment comprises at least one location where the drape is temporarily secured and also provides a sterile field about the at least one longitudinal access, yet may be sterilely separated about this longitudinal access by one of a variety of mechanisms and configurations of the surgical drape. As shown in FIGS. **2**A-D this longitudinal sterile separation may be accomplished by a series of overlapping and temporarily attached draping segments (see 4, 6, 8, 10 in FIG. **1**C), which is referred to hereinafter as the 'double-underbite' configuration. This double-underbite may further comprise at least one serrated portion of the surgical drape which may become detached by pulling or tearing the surgical drape material at the serrated location. Preferably, as shown in FIG. **1**D, this serrated location is not exposed to non-sterile equipment.

FIGS. **1**A-**1**D depict a drape **2** according to one embodiment wherein portions of the drape **2** comprise overlapping features 4, 6, 8, 10 comprising a selectively detachable portion. Overlapping features 4, 6, 8, 10 generally define a sterile area **20** that may be detached in order to remove the drape **2** from a patient and/or workspace.

According to alternate embodiments, this serrated portion of the surgical drape may include serrated portions in multiple locations (see FIG. **2**A, **22**). In other embodiments, the surgical drape may include at least one zip strip (FIG. **2**B, **25**) in addition to a serrated portion of the drape (FIG. **2**B, **23**, FIG. **2**C, **24**), which may also become separated from the adjoining portion of the surgical drape. According to the embodiment shown in FIG. **2**C, the zip strip may be located on an alternative or additional location of the drape relative to the patient (see FIG. **2**C, **26**).

Other aspects of the invention are shown in FIG. **1**C, which includes an under-table wrapping element **12**, **14**, which is achieved by including fastening devices with each of the overlapping lower portions of the surgical drape **2** where those lower portions overlap **12**, **14**. A variety of different fastening devices are contemplated for use with the present disclosure, including but not limited to adhesive devices, pins, clips, snaps, hook and loop devices, velcro, magnetic strips, etc.

This design offers navigation readability of a reference frame through sterile overlying plastic cover (or lens), contains an under table wrapping component for easy positioning of 3D radiographic device (or C-arm, O-arm) to and from field, and allows for a simple two step sterile separation of approximated longitudinal sides (e.g. 'underflap' and 'double underbite'). The RWD1 preferably includes a plastic drape and/or has a plastic component (or lens) for navigation readability.

RWD1 variants may comprise transparency to light and/or transmissivity to various known radiographic devices (see FIGS. **1**A-**4**B). For example, the entire drape may be made of transparent and/or translucent plastic. Alternatively, a built-in clear plastic (or other transparent material) section of drape may be provided to allow for readability of the reference frame by navigation technology (see FIGS. **3**A-B, ref no. **30**). This plastic section is situated to accommodate for various positions of the reference frame on the patient to include cervical, thoracic, lumbar, as well as bilateral sacroiliac. The plastic region may further accommodate a variety of ana-

tomic placement of the reference frame by one of several mechanisms, by way of example but not limitation: longitudinal sterile separation extending most if not the entire length of the drape.

FIGS. **3**A-B depict one embodiment of the drape wherein a separable portion **28** adapted to maintain a sterile field generally extends along a longitudinal length of the drape. A transmissive or translucent portion **30** comprising at least a portion of the width of the drape and extending along the length of the drape is provided. It will be expressly understood that this portion **30** may be of various dimensions and, in alternative embodiments, does not extend along the entire width or length of the drape.

In various embodiments, one or more transparent portions or lenses may be placed at various locations (FIGS. **4**A-B, **32**) on the drape **3** to accommodate for different anatomic positions. Plastic may be incorporated into just a portion of the drape (either inferior or superior) as shown in FIG. **3**B, yet with the ability to reverse the orientation of the drape when placing it thus again accommodating for different anatomic positions. Such concepts also apply when accommodating for use of the reference frame in ENT procedures, brain surgery, and pelvic surgery among other types of surgeries utilizing navigation technology. Although FIGS. **1**A-**4**B are depicted with a 'double underbite' separation, it is expressly understood that any of the other separation designs including but not limited to the 'single-underbite' and 'Z-Shaped' separation designs described herein may be substituted.

Referring to FIGS. **1**A-**3**B, the draping device preferably comprises at least one sterile separation element, which may extend longitudinally the entire or less than the entire length of the draping device. As shown in the Figures, the superior aspect of the separation element falls on the inferior aspect of the separation element, thereby overlapping and protecting the separation seam and the unsterile edge of the draping device from contacting the underlying sterile field.

Sterile separation of longitudinal effaced sides (see FIGS. **1**A-**8**D) provides several advantages: it has the unique ability for the two longitudinally effaced lateral sides to separate and fall away to their ipsilateral side in a simple (one or two step) sterile fashion. Thus, as shown in the appended drawing figures, multiple unique designs for a surgical drape are disclosed that allow preservation of sterile edges of both separating sides, including the 'double underbite' (depicted in FIGS. **1**A-**4**B), 'peel away flap cover' (FIGS. **5**A-C, **36**), 'single underbite' (FIGS. **6**A-C, **38**), 'curled lip' (FIGS. **7**A-D, **40***a*, **40***b*), and 'underflap' (FIGS. **8**A-D, **50**). Various means of initial connection are utilized, including but not limited to the following: serration, static, tacking, seam weld, zip strip, adhesive, tape/steristrip, among others listed herein.

FIGS. **8**A-D depict an embodiment wherein the underflap design **50** is provided. As shown, a separation area may be covered by a pleat **52** which covers and/or protects additional areas of the drape **54**, **56** in a first position. The underflap may be opened and separated along a predetermined tear line or separation point as described herein. In at least one embodiment, a longitudinal score line or separation point is disposed below the pleat **52** as shown in FIG. **8**D.

The under-table wrapping component (see FIGS. **9**A-C) has the following features: each lateral side hanging over the table connects underneath by a variety of means **62** thereby enclosing all hanging wires, catheters, and other medical equipment commonly located under the OR table and at risk of getting 'snagged' by the entering and exiting 3D radiographic device (or C-arm). The two hanging sides **66**, **68** of the drape connect under the table by various means **62**, including but not limited to the following: velcro, adhesive, static, buttons, cloth (or other material) ties among others. Straps with such connections may further or alternatively be utilized. These various connective possibilities are adjustable and configurable in quantity and location, and thus accommodate for different overall circumferences as table frame size, patient size, and arm positioning all can possibly alter this measurement.

Referring now to FIGS. **10**A-**13**B, another embodiment of the surgical drape (RWD2) has been designed to meet all basic design requirements considered to be mandatory for operating room use. RDW2 variants contain the same essential design characteristics as RWD1 yet adds the ability to provide the surgeon the option of direct exposure of a reference frame **77** (with minimal potential sterility compromise). This specific design provides all three major aspects of RWD1 described above, but provides the option of leaving the frame exposed directly to the navigation device if desired by the surgeon. As shown, a portion **72** of the drape may be gusseted or extended in a manner that allows for selective displace of the portion **72** with disrupting or contaminating a remainder of the drape. Accordingly, a portion of an underlying patient may be exposed when access is required or desired for various procedures without complete removal of the drape.

As is the case with RWD1, more than one design variant is disclosed below. (See FIGS. **10**A-**13**B). The surgeon may allow for direct exposure after the drape has been placed with complete coverage of the underlying sterile field (as the initial design provides in RWD1). The direct exposure option keeps the underlying field sterile with the only exception being that of the protruding neck and reference frame itself. If the surgeon believes the accuracy of information is comprised by the overlying plastic cover or lens, he/she may decide to utilize this 'direct' option at the slight potential compromise of sterility. The surgeon, if executing this option, still benefits from the temporary sterile coverage of the rest of the field. The under-the-table wrapping feature (to make positioning of the radiographic device safer, quicker, and easier), and the efficiency of the removal process as both sides of the drape seamlessly fall away to their respective sides is further incorporated with the surgical drape in this embodiment.

In the embodiment referred to as RWD2 (as depicted in FIGS. **10**A-**13**B), the reference frame **77** is placed through the drape **70** by separating a small portion **72** of the serrated connection of the two opposing sides. In the 'direct' version (meaning direct visualization of the reference frame by the navigation monitor), the overlying plastic slip **72** is partially pulled back (depicted in FIGS. **10**A-**11**C and **13**A-B) or a component of the cover slip is reflected back (depicted in FIG. **12**). Given the undraped radiographic device above, there exists a potential breach in sterility and thus this option must be considered in a risk-benefit analysis by the surgeon prior to execution. Under-table or below-patient wrapping features as shown and described herein are also incorporated into various embodiments of the RWD2. As shown and described in FIGS. **9**A-C, fasteners **62** may be provided at or near opposing ends of the drape to secure the opposing ends to one another or additional objects. As an upper or patient-side portion of the drape comprises features for separating and/or detaching the drape from a patient, fasteners **62** may be selectively reversible/detachable fasteners, or may permanently affix to one another.

FIGS. **11**A-C depict yet another embodiment of the present invention where one or more fasteners **82** are provided along a longitudinal length of an upper portion of the drape **80**.

Selectively detachable portions and translucent or transmissive materials **88** may be provided in addition to various fasteners **82**.

FIG. **12** depicts an embodiment of a drape **81** provided with a plurality of hinged portions **90** which allow for selective access to various regions or objects disposed under the drape.

FIG. **13**A-B depict yet another embodiment wherein a hinged portion **92** and corresponding flap **94** are provided for selective access. These features **92**, **94** allow for access to a surgical workspace and/or exposure of a reference frame **77**.

For the purpose of streamlining the present disclosure, Applicants hereby incorporate by reference U.S. Provisional Patent Application Nos. 61/352,045 and 61/357,637 herein in their entireties. The drape disclosed in these two prior filed provisional patent applications have been designed to meet all basic design requirements considered to be mandatory for operating room use. For those surgeons who remain highly concerned about the potential inaccuracy of the readability of the reference frame by the navigation monitor through a transparent plastic cover or lens for that matter, yet at the same time are unwilling to accept any potential slight breach in sterility (such as in RWD2 where reference frame is left exposed to overlying radiological device as an option), a unique alternate design to address such a concern is provided. This alternate design will be referred to as RWD4.

The RWD4 is a one piece customized disposable surgical drape to be used in any surgery that involves one of the following technologies: (1) stand alone non-draped 3D image acquisition device (requiring greater than 180 degrees of orbital rotation); and (2) image-guided navigation technology. This RWD4 drape accommodates a surgeon's preference, as it allows for both indirect (through plastic or lens) as well as direct navigation readability of the reference frame while the 3D acquisition is taking place.

This drape is different, however, from RWD2 in that in both instances (direct and indirect navigation readability of the reference frame) it maintains sterility of the field to include the protruding reference frame. This drape is modifiable in that the concepts may be adapted to accommodate different anatomical placements of the reference frame and/or various positions of the monitor.

This drape has utility in other surgeries (in addition to spine surgery) such as the pelvic trauma, brain surgery, ENT surgery among others. The 'Frame Hood Cover' is the unique aspect of RWD4 that is designed to cover and protect the reference frame (with attached neck) from the above non-draped (and thus unsterile) 3D radiological device (e.g. O-arm). It is made of a clear, thin plastic to allow navigation readability of the reference frame through the 'Frame Hood Cover' as the 3D data acquisition is taking place. At the same time, it allows for direct and open-air readability by the navigation monitor (rather than through the plastic) in that the 'Frame Hood Cover' is able to be partially open while concomitantly maintaining 'above the reference frame' protection from the directly overlying 3D radiographic device.

FIGS. **14**A-B provide additional end views of yet another sterility maintaining feature that may be employed in various embodiments. As shown, a drape comprises upper **100***a* and lower **100***b* superior portions as well as upper **102***a* and lower **102***b* inferior portions. One or more separable portions and/or fasteners for securing the drape as described herein and as will be recognized by one of ordinary skill in the art may be provided. The drape may be separable at numerous different locations. For example, separable portion(s) may connect upper superior portion **100***a* to lower superior portion **100***b*, lower superior portion **100***b* to upper inferior portion **102***a*, upper inferior portion **102***a* to lower inferior portion **102***b*, and/or may be connected/provided at the intersections **104** of these features.

When the drape is separated and removed or allowed to fall, upper superior portion **100***a* will fall to upper inferior portion **102***a* and lower superior portion **100***b* will fall to lower inferior portion **102***b*. Accordingly, superior portions **100***a,b* which are exposed to various contaminants are prevented from contacting and/or contaminating a patient and/or a workspace by virtue of the dimensions and positioning of the inferior portions **102***a,b*. As shown, superior portions **100***a,b* cover the entire surface area of the inferior portions **102***a,b* in at least a first position of use. Contamination of inferior portions **102***a,b* from, for example, radiographic and imaging equipment is thus prevented. Upon separation and removal of the drape, contamination of the underlying workspace and/or patient is likewise prevented by inferior portions **102***a,b*.

FIG. **14**B further depicts removal of the drape subsequent to detachment of a selectively securable feature and wherein portions of the drape are transmitted as shown by directional arrows **106**. As shown, potentially contaminated upper and lower superior portions **100***a,b* are prevented from contacting a sterile space by upper and lower inferior portions **102***a,b*.

As with any radiographic and/or navigation device, the surgeon understands that these technologies serve merely as tools created to assist the surgeon in his/her task. All tools utilized in surgery have known limitations and can never be utilized with 100% reliance. According to one embodiment, an alternative design that utilizes a high light transfer lens incorporated into the plastic (or other material as clear plastic is no longer necessary if a lens is incorporated) covering the reference frame is provided to further diminution of light reflection and further enhancement of clear vision. This lens can be flat or dome shaped.

While various embodiment of the present disclosure have been described in detail, it is apparent that modifications and alterations of those embodiments will occur to those skilled in the art. However, it is to be expressly understood that such modifications and alterations are within the scope and spirit of the present disclosure, as set forth in the following claims.

The foregoing discussion of the disclosure has been presented for purposes of illustration and description. The foregoing is not intended to limit the disclosure to the form or forms disclosed herein. In the foregoing Detailed Description for example, various features of the disclosure are grouped together in one or more embodiments for the purpose of streamlining the disclosure. This method of disclosure is not to be interpreted as reflecting an intention that the claimed disclosure requires more features than are expressly recited in each claim. Rather, as the following claims reflect, inventive aspects lie in less than all features of a single foregoing disclosed embodiment. Thus, the following claims are hereby incorporated into this Detailed Description, with each claim standing on its own as a separate preferred embodiment of the disclosure.

Moreover, though the present disclosure has included description of one or more embodiments and certain variations and modifications, other variations and modifications are within the scope of the disclosure, e.g., as may be within the skill and knowledge of those in the art, after understanding the present disclosure. It is intended to obtain rights which include alternative embodiments to the extent permitted, including alternate, interchangeable and/or equivalent structures, functions, ranges or steps to those claimed, whether or not such alternate, interchangeable and/or equivalent struc-

tures, functions, ranges or steps are disclosed herein, and without intending to publicly dedicate any patentable subject matter.

What is claimed is:

1. A surgical drape, comprising:

an area defined by a predetermined length and a predetermined width;

a selectively separable portion extending along a longitudinal portion;

the selectively separable portion intersecting a lateral point proximal to a midpoint of the predetermined width;

a first peripheral edge at a first terminus of the predetermined width and a second peripheral edge at a second terminus of the predetermined width, the first and second peripheral edges adapted to at least partially overlap one another;

wherein the first peripheral edge comprises a bifurcated edge having a first superior portion and a first inferior portion and the second peripheral edge comprises a bifurcated edge portion having a second superior portion and a second inferior portion, the bifurcated edges adapted to contact each other in a double-overlap manner such that at least a portion of the first inferior portion is disposed on top of at least a portion of the second inferior portion, and at least a portion of the first superior portion is disposed on top of at least a portion of the second superior portion, such that the overlapping portions in combination create four distinct layers of material in a closed position and generally define a sterile area that may be detached to remove the drape;

at least a portion of the area being substantially transmissive to a radiographic device;

wherein the selectively separable portion maintains a sterile field at the points of separation; and

wherein the selectively separable portion comprises a peel away flap cover extending substantially the entire length of the selectively separable portion.

2. The surgical drape of claim **1**, wherein the lateral point proximal to the midpoint of the predetermined width is within a middle third of the predetermined width.

3. The surgical drape of claim **1**, wherein the lateral point proximal to the midpoint is a point equidistant from the first peripheral edge and the second peripheral edge.

4. A surgical drape for maintaining a sterile field, comprising:

a predetermined length between a first end and a second end;

a predetermined width between a third end and a fourth end;

the predetermined length being greater than the predetermined width;

a sterile separable portion extending between the first end and the second end, the sterile separable portion comprising a first bifurcated edge at the third end, the first bifurcated edge comprising a first superior and a first inferior portion and a second bifurcated edge at the fourth end, the second bifurcated edge comprising a second superior portion and a second inferior portion, wherein the bifurcated edges are adapted to contact each other in a double-overlap manner such that at least a portion of the first inferior portion is disposed on top of at least a portion of the second inferior portion, and at least a portion of the first superior portion is disposed on top of at least a portion of the second superior portion;

the sterile separable portion intersecting a lateral point proximal to a midpoint of the predetermined width;

at least a portion of the drape being substantially transmissive to a radiographic device; and

wherein the selectively separable portion maintains a sterile field; and

wherein the selectively separable portion comprises a peel away flap cover extending substantially the entire length of the selectively separable portion.

5. The surgical drape of claim **4**, the selectively separable portion being generally parallel with the third end and the fourth end.

6. The surgical drape of claim **4**, wherein the lateral point proximal to the midpoint of the predetermined width is within a middle third of the predetermined width.

7. The surgical drape of claim **4**, wherein the lateral point proximal to the midpoint is a point equidistant from the third end and the fourth end.

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